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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,181	12/09/2003	Navpreet Singh	SP-1310	6222
44388	7590	02/23/2009	EXAMINER	
Solae, LLC 4300 Duncan Avenue Legal Department E4 St. Louis, MO 63110			WEIER, ANTHONY J	
			ART UNIT	PAPER NUMBER
			1794	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,181	Applicant(s) SINGH ET AL.	
	Examiner Anthony Weier	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 41-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/19/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. This application contains claim drawn to an invention nonelected with traverse in the reply filed on 3/31/08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Terminal Disclaimer

2. The terminal disclaimer filed 11/19/08 is not proper. An attorney or agent, not of record, is not authorized to sign a terminal disclaimer in the capacity as an attorney or agent acting in a representative capacity as provided by 37 CFR 1.34 (a). See 37 CFR 1.321(b) and/or (c).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims, 4, 6, 14, 16, 24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Dependent claims 4, 14, and 24 do not further limit the claims and, in fact, broaden the limitation of protein content beyond that recited in the respective independent claims.

Dependent claims 6, 16, and 26 are indefinite in that they appear to contradict the protein content limited in the respective independent claims by calling for a protein

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content of at least 90 weight percent.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-37 and 39 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 11/240212 taken together with Schweiger et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims deal significantly with the same protein material only expressed in different ways or differing combinations of claim limitations. It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the composition defined in the claims of 11/240212 to have defined the soy protein material by measuring, for example, the lard gel strength rather than or in

addition to the pork back fat emulsion strength as set forth in 11/240212 as a matter of preference depending on the particular tests desired in defining the soy protein composition.

The claims further call for the soy protein material to be derived from an alcohol washed soy protein concentrate. It is well known to increase the purity of soy protein concentrate toward or to an isolate form using an alcohol wash to remove polysaccharides therein. For example, Schweiger et al et al teaches just such a treatment (col. 1, lines 9-21). It would have been further obvious to have provided a material with increased protein value and better flavor as taught in Schweiger et al.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4, 6-14, 16-24, and 26-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamato et al.

Yamato et al discloses a soy protein material that is prepared in a manner very

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similar to the method as set forth in the instant specification and, as such, is considered to possess the particular claimed product characteristics regarding gel and emulsification strength limitations. In particular, Yamato et al discloses treatment of soy protein by water extracting same in a slurry with a pH of less than 6, removal of the precipitate (or separation of soluble material), neutralizing same and then subjecting the neutralized soy protein material to a heat. In Yamato et al, the protein created is considered to have excellent gel forming ability and possesses a high emulsion stability when mixed with a pork fat (lard; see Example 1 and claims). Yamato et al further discloses preparing a protein powder that is 86.45% protein (Example 2) but which would be 90% (and therefore a protein isolate) if calculated on a dry basis (i.e. not including the 4.25% water; calculated from $86.45/(100-4.25)$). Yamato et al further discloses the use of the soy protein product in food products including, for example, meat products (see col. 5, lines 44-45).

9. Claims 1-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Monagle et al.

Monagle et al discloses a soy protein material that is prepared in a manner very similar to the method as set forth in the instant specification and, as such, is considered to possess the particular claimed product characteristics regarding gel and emulsification strength limitations. In particular, Monagle et al discloses treatment of soy protein by water extracting same in a slurry with a pH of, for example, 5, removal of the precipitate, neutralizing same and then subjecting the neutralized soy protein material to heat (e.g. claims). In Monagle et al, the protein created is considered to have firm,

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strong, gel forming ability. Monagle et al further discloses preparing a protein powder that is, for example, 82% protein on a dry basis (col. 2) as well as protein isolates which inherently have a protein content above 90% (e.g. Example 7). Monagle et al further discloses the use of the soy protein product in food products including, for example, meat products (see Examples).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamato et al or Monagle et al.

If it is shown that Yamato et al or Monagle et al do not produce a product having the particular emulsification and gel strength values called for in the instant claims, it should be noted that each reference provides guidance as to how one may improve such variables (Yamato et al, col. 4; Monagle et al, col. 8 and adjacent Table). It would have been obvious to one having ordinary skill in the art at the time of the invention to have arrived at such values through routine experimental optimization using the suggested variable manipulation set forth in Yamato et al.

Yamato et al discloses only the preparation of a soy protein product of about 86% protein and is silent regarding the preparation of a soy product having a protein content between 75 and 85 % on a moisture free basis. However, the purity of the

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protein would be dependent on the particular source of the protein used as well as, for example, the length of time for extraction and particular separation performance employed. It would have been further obvious to have arrived at such protein content as a matter of preference depending on the particular protein started with (depending on availability, cost, etc.) as well as the allowed time and cost involved with the extraction process and, therefore, degree of desired purity permitted in the soy protein product.

12. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamato et al or Monagle et al and taken together with either one of Altemueller et al or Egbert et al.

The claims further call for the use of said soy protein gel in dairy food products. However, it is well known to employ soy protein gels not only in meat products but dairy foods as well as taught, for example, by either one of Altemueller et al (Abstract; col. 14; col. 29, lines 32-37) or Egbert et al (Abstract; paragraphs 5, 53, and 55). It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the soy protein gelling powder of Yamato et al or Monagle et al in dairy as well as meat products as an alternative use for such functional food ingredient.

Applicant's Arguments

13. Applicant's arguments filed 11/19/08 have been fully considered but they are not persuasive.

Applicant argues that the prior art references teach away from the soy protein product of the instant invention since same employs different/other steps. It should be first noted that the instant claims are all directed to the product of the instant invention.

The instant claims are broad enough to encompass the soy protein products of the applied prior art, and there is nothing in the instant claims that provide limitations of the product itself that are not present or are different than those one may attribute to the products of the applied prior art references.

Applicant argues that Monagle et al teaches preparing a protein product from only a soluble fraction of soy flake and does not teach a process which uses an insoluble fraction of a soy protein concentrate to obtain a soy protein material having a high gel strength. It should be first noted that although Monagle et al does disclose an embodiment wherein a soy protein product is produced wherein most but not all insoluble components have been removed (see col. 4). Nevertheless, the instant product claims recite no requirement that the protein material must be made from the insoluble or both soluble and insoluble fractions of a soy protein concentrate. Again, the instant claims are recited broadly enough to include soy protein products derived from almost fully soluble fractions taken from a soy source as set forth in the embodiment of Monagle et al discussed above.

All other arguments are addressed in view of the rejections set forth above.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Weier whose telephone number is 571-272-1409. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Anthony Weier
February 13, 2009